

Exhibit A

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products
Liability Litigation,

No. MDL15-2641-PHX-DGC

Doris Jones, an individual,

Plaintiff,

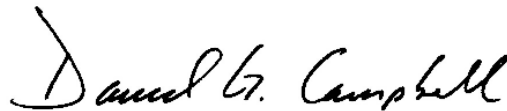
v.

C. R. Bard, Inc., a New Jersey corporation;
and Bard Peripheral Vascular, Inc., an
Arizona corporation,

Defendants.

JURY INSTRUCTIONS

DATED: _____



David G. Campbell
United States District Judge

INSTRUCTION NO. 1

Members of the Jury: Now that you have heard all of the evidence, it is my duty to instruct you on the law that applies to this case.

A copy of these instructions will be sent to the jury room for you to consult during your deliberations.

It is your duty to find the facts from all the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you whether you agree with it or not. And you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that you took an oath to do so.

Please do not read into these instructions or anything that I may say or do or have said or done as indicating that I have an opinion regarding the evidence or what your verdict should be.

INSTRUCTION NO. 2

Although there are two defendants in this case, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., you should decide the case as to the two defendants jointly. As a result, in these instructions and in the verdict form, we will refer to defendants collectively as “Bard.” Unless otherwise stated, the instructions apply to both Bard and Mrs. Jones.

INSTRUCTION NO. 3

The evidence you are to consider in deciding what the facts are consists of:

1. the sworn testimony of the witnesses;
2. the exhibits that are admitted into evidence;
3. any facts to which the lawyers have agreed; and
4. any facts that I have instructed you to accept as proved.

INSTRUCTION NO. 4

In reaching your verdict, you may consider only the testimony of the witnesses, the exhibits received into evidence, and facts to which the parties have agreed.

Certain things are not evidence, and you may not consider them in deciding what the facts are. I will list them for you:

1. Arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they have said in their opening statements, may say in closing arguments and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls.
2. Questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection or by the court's ruling on it.
3. Testimony that is excluded or stricken, or that you were instructed to disregard, is not evidence and must not be considered. In addition, some evidence is received only for a limited purpose; when I instruct you to consider certain evidence only for a limited purpose, you must do so and you may not consider that evidence for any other purpose.
4. Anything you may have seen or heard when the court was not in session is not evidence. You are to decide the case solely on the evidence received during the trial.

INSTRUCTION NO. 5

Some exhibits admitted into evidence have been partially “redacted,” which means that certain contents of the exhibits have been blacked out or whited out. The parties and I have redacted information that is not properly admitted as evidence. You may give the unredacted information in any exhibit whatever weight you choose, but you must disregard the redacted information and must not speculate about what it might say.

INSTRUCTION NO. 6

You have heard testimony from a number of witnesses who testified to opinions and the reasons for their opinions. This opinion testimony is allowed because of the education or experience of those witnesses.

Such opinion testimony should be judged like any other testimony. You may accept it or reject it, and give it as much weight as you think it deserves, considering the witness's education and experience, the reasons given for the opinion, and all the other evidence in the case.

INSTRUCTION NO. 7

Federal law prohibits current FDA employees from testifying in court regarding any function of the FDA, and prohibits current and former FDA employees from testifying about information acquired in the discharge of their official duties, without authorization of the Commissioner of the FDA. As a result, neither side in this case was able to present testimony from current FDA employees or former FDA employees regarding the discharge of their duties related to this case.

INSTRUCTION NO. 8

Certain charts and summaries not admitted into evidence have been shown to you in order to help explain the evidence in the case. These have been referred to as demonstrative exhibits. The demonstrative exhibits are only as good as the underlying evidence that supports them. You should, therefore, give them only such weight as you think the underlying evidence deserves.

INSTRUCTION NO. 9

Certain charts and summaries have been admitted into evidence to illustrate information brought out in the trial. Charts and summaries are only as good as the testimony or other admitted evidence that supports them. You should, therefore, give these only such weight as you think the underlying evidence deserves.

INSTRUCTION NO. 10

All parties are equal before the law and a corporation is entitled to the same fair and conscientious consideration by you as any party.

INSTRUCTION NO. 11

Under the law, a corporation is considered to be a person. It can only act through its employees, agents, directors, or officers. Therefore, a corporation is responsible for the acts of its employees, agents, directors, and officers performed within the scope of authority.

INSTRUCTION NO. 12

Mrs. Jones asserts four claims against Bard: (1) Strict Product Liability Based on Design Defect; (2) Strict Product Liability Based on Failure to Warn; (3) Negligent Design; and (4) Negligent Failure to Warn. I will instruct you on the law that applies to each of these claims. You should consider each claim separately.

INSTRUCTION NO. 13

Before I give you instructions about Mrs. Jones' specific claims, let me give you a few instructions that will apply to all of the claims.

When a party has the burden of proving any claim or affirmative defense by a "preponderance of the evidence," it means you must be persuaded by the evidence that the claim or affirmative defense is more probably true than not true. You should base your decision on all of the evidence, regardless of which party presented it.

Some instructions will state that you must find that an event or condition or action was the "proximate cause" of Mrs. Jones' injury. Proximate cause means that cause which, in a natural and continuous sequence, produces an event, and without which cause such event would not have occurred. Thus, when I use the expression "proximate cause," I mean a cause that, in the natural or ordinary course of events, produced Mrs. Jones' injury.

In order to be a proximate cause, the act or omission complained of must be such that a person using ordinary care would have foreseen that the event, or some similar event, might reasonably result.

There may be more than one proximate cause of an event. Thus, to prove proximate cause, Mrs. Jones need not prove that an act or omission was the only cause or the last or nearest cause. It is sufficient if it combines with another cause resulting in the injury. However, if an act or omission of any person not a party to the suit was the sole proximate cause of an occurrence, then no act or omission of any party could have been a proximate cause.

INSTRUCTION NO. 14

Mrs. Jones contends that Bard is strictly liable because of a defective design of the Eclipse IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable. To recover damages for strict product liability based on a design defect, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the product was defectively designed;

Second, the design defect existed at the time the product left the control of Bard; and

Third, the design defect in the product was a proximate cause of Mrs. Jones' injury.

There is not a single general way to define what constitutes a design defect in a product. Whether or not a product is defective is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence that has been received during the trial.

Although Bard is not required to ensure that a product design is incapable of producing injury, it has a duty to exercise reasonable care in choosing the design for a product.

To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefits of that product design. You must decide whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including the following factors:

- 1) the usefulness of the product;
- 2) the severity of the danger posed by the design;
- 3) the likelihood of that danger;
- 4) the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and common knowledge or the expectation of danger;

- 5) the user's ability to avoid the danger;
- 6) the technology available when the product was manufactured;
- 7) the ability to eliminate the danger without impairing the product's usefulness or making it too expensive;
- 8) the feasibility of spreading any increased cost through the product's price;
- 9) the appearance and aesthetic attractiveness of the product;
- 10) the product's utility for multiple uses;
- 11) the convenience and durability of the product;
- 12) alternative designs of the product available to the manufacturer; and
- 13) the manufacturer's compliance with industry standards or government regulations.

In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Mrs. Jones' injury. In determining the reasonableness of the product design chosen by Bard, you should consider:

- 1) the availability of an alternative design at the time Bard designed this product;
- 2) the level of safety from an alternative design compared to the actual design;
- 3) the feasibility of an alternative design, considering the market and technology at the time the product was designed;
- 4) the economic feasibility of an alternative design;
- 5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and
- 6) any adverse effects on Bard or the product from using an alternative design.

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal or state safety and non-safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

In deciding whether the design of the Eclipse filter was defective, you may also consider whether the FDA instituted regulatory action with respect to the Eclipse filter. However, a product may be defective even if the FDA institutes no regulatory action.

If you decide that the risk of harm in the product's design outweighs the utility of that particular design, then the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design, and the product is defective. If after balancing the risks and utility of the product, you find by a preponderance of the evidence that the product suffered from a design defect that proximately caused Mrs. Jones' injury, then Mrs. Jones is entitled to recover.

Defendants' Objections:

Bard objects to Plaintiff's proposed deletions (highlighted in yellow) because she has deleted two necessary elements from this instruction as given in *Booker*. First, Plaintiff deleted the paragraph that refers to considering compliance with industry standards or government regulations, which is an element of the risk utility test set forth by the Georgia Supreme Court, and for which a separate jury instruction was created. See, Ga. Civil Pattern Instruction 62.670 below:

62.670 Strict Liability; Design Defect; Compliance with Industry Standards or Government Regulations

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal or state safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

Banks v. ICI Americas Inc., 264 Ga. 732 (1994); *Doyle v. Volkswagenwerk Artengesellschaft*, 267 Ga. 574 (1997)

Second, Plaintiff also deleted the paragraph regarding regulatory action. However, under Georgia law when a plaintiff claims a design defect in a widely-distributed product, “[t]he fact that . . . [defendant] had never been subjected to regulatory action with respect to the claimed defect . . . tends to negate the allegation that the configuration was a dangerous design.” *Browning v. Paccar, Inc.*, 214 Ga. App. 496, 498, 448 S.E.2d 260, 263 (1994). As such, “evidence that the customary methods for protecting the public from defective [products] had not been instituted in connection with these [products] was relevant to show defendant’s design and manufacture was not negligent.” *Id.*

Bard requests that the instruction as given in *Booker* be used.

Plaintiff’s Response:

Plaintiff acknowledges that she seeks modification of the instruction given in *Booker*. However, for the reasons stated in *Booker*, Bard’s proposed language provides undue emphasis on FDA evidence, drawing the jury’s attention to FDA actions and inactions on three separate occasions. This results in an emphasis or comment on certain types of evidence as more important than other factors. Plaintiff requests that the language highlighted in yellow be deleted.

INSTRUCTION NO. 15

Mrs. Jones contends that Bard is strictly liable because it failed to give adequate warnings regarding the Eclipse IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of an inadequate warning with respect to the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

To recover damages for strict liability based on an inadequate warning, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the warning given with the product was inadequate;

Second, the inadequate warning existed at the time the product left the control of Bard; and

Third, the inadequate warning was a proximate cause of Mrs. Jones' injury.

There is no single general way to define what constitutes an inadequate warning in a product. Whether or not a warning is inadequate is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence received during the trial.

Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its Eclipse IVC filter. Bard owes this duty to warn to all physicians whom the manufacturer should reasonably foresee may use the product. Bard's duty to warn may have been breached by:

- a) failing to provide an adequate warning of the ECLIPSE filter's potential dangers or
- b) failing to adequately communicate to Mrs. Jones' physicians the warning provided.

A manufacturer's duty to warn arises when the manufacturer knows or reasonably should know of the danger presented by the use of the product. Therefore, a manufacturer

has a continuing duty to adequately warn of defects in a product even after that product has left the control of the manufacturer.

You must decide whether adequate efforts were made by Bard to communicate all risks that were known or reasonably should have been known to Bard, to the physician who implanted the ECLIPSE filter in Mrs. Jones, and whether the warning that Bard communicated was adequate.

A product, however well or carefully made, that is sold without an adequate warning of such danger, may be said to be in a defective condition. If you find by a preponderance of the evidence that Bard did not adequately warn when an adequate warning should have been given, and that this inadequate warning proximately caused Mrs. Jones' injury, then you may find the ECLIPSE filter to be defective and for that reason, find that Mrs. Jones is entitled to recover.

INSTRUCTION NO. 16

Mrs. Jones claims that Bard was negligent in the design of the Eclipse IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

- (1) Bard had a duty of reasonable care to Mrs. Jones,
- (2) Bard breached that duty in the design of the Eclipse filter,
- (3) the breach was a proximate cause of Mrs. Jones' injury, and
- (4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances. In making the determination of whether Bard acted reasonably, you should consider the risk-benefit analysis for design defect about which I previously instructed you.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in the design of the Eclipse filter she received.

Plaintiff's Objection:

Plaintiff proposes that the instruction from Booker be given, with name and product information modified. Bard's proposed language (highlighted in blue) would confuse the negligent design instruction with the strict product liability instruction making risk/benefit a de facto element of both claims and unnecessarily emphasizing this aspect of the claim.

Defendants' Response:

Defendants request that the language highlighted in blue be added to make the instruction consistent with Georgia law. See, *Ogletree v. Navistar International Transportation Corporation*, 271 Ga. 644 (1999), in which the Georgia Supreme Court held, "In a negligent design case, the risk-utility analysis applies to determine whether the manufacturer is liable. Thus, the mandate that a product's risk must be weighed against its utility incorporates the concept of "reasonableness" so as to apply negligence principles in the determination of whether the manufacturer defectively designed its product. (Citations omitted)."

INSTRUCTION NO. 17^[1]

Mrs. Jones claims that Bard was negligent in failing to warn Dr. Avino about the risks of the Eclipse IVC filter she received he Dr. Avino implanted in her. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

- (1) Bard had a duty of reasonable care to Mrs. Jones warn about the risks of the Eclipse IVC filter,
- (2) Bard breached that duty in the adequacy of the warnings about the Eclipse filter provided to Dr. Avino,
- (3) the breach was a proximate cause of Mrs. Jones' the her injury, and
- (4) she suffered damages.

The parties agree that Bard had a duty of reasonable care to warn about the risks of the Eclipse IVC filter.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances. In making the determination of whether Bard acted reasonably in warning Dr. Avino, you should consider the same factors for strict liability failure to warn about which I previously instructed you.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the risks of the Eclipse filter she received.

The parties agree to the changes highlighted in green.

Plaintiff's Objection:

Plaintiff objects only to the highlighted text (in blue) added by Defendants. The proposed reference back to the strict liability instruction will be confusing to the jury since it would send the message that it is deciding the same issue for both claims when such claims are separate and distinct. *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999^[2]).

Defendants' Response:

Bard objects to the sentence added by Plaintiff (highlighted in yellow) as duplicative of element number 1, and not necessary. The highlighted (in blue) language should be added to make the instruction proper under Georgia law. Under Georgia law, whether premised on negligence or strict liability, Plaintiff must prove that “Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its filter. *Shelton v. GALCO Int’l, Ltd.*, No. 3:16-CV-00033-TCB, 2017 WL 3597497 (N.D. Ga. July 19, 2017) (quoting *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)) (“[T]he duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of the product.”). Further, Plaintiff’s reliance on *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999) is misplaced. While the Georgia Courts acknowledge that there are two separate causes of action, they also recognize that the same duty based elements apply to both strict liability and negligent failure to warn. J. Kennard Neal and Catherine Payne, *Ga. Products Liability Law* § 8:1 (4th ed. 2018) (“Georgia has traditionally recognized failure to warn claims arising both in negligence and in strict liability. [H]owever, Georgia courts make no distinction between the two, but apply the same duty concepts and the same tripartite test of foreseeability.”) (citations omitted); *Id.* at § 2:1 (“[I]n examining either type of claim, Georgia courts have consistently applied the same duty-based negligence analysis.”)

PLAINTIFF'S PROPOSED INSTRUCTION RE MANUFACTURER'S SCOPE OF KNOWLEDGE

PRODUCTS LIABILITY – DEFECT DUE TO INADEQUATE WARNING;
MANUFACTURER HELD TO THE KNOWLEDGE AND SKILL OF AN EXPERT

In cases such as the instant case, a manufacturer is held to the knowledge and skill of an expert. This is relevant in determining (1) whether the manufacturer knew or should have known of a danger in its product and (2) whether the manufacturer was negligent in failing to communicate this superior knowledge. The manufacturer's status as an expert means that at a minimum, it must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imported thereby.

Even more importantly, a manufacturer has a duty to test and inspect its product. The extent of research and experiment must be commensurate with the dangers involved. A product must not be made available without disclosures of these dangers that the application of reasonable foresight would reveal. Nor, may a manufacturer rely unquestioningly on others to sound such disclosure concerning a danger in this product. Rather, each manufacturer must bear the burden of showing that its own conduct was proportionate to the scope of its duty.

Borel v. Fibreboard Paper Prods., Corp., 493 F.2d 1076, 1080-1090 (5th Circuit); *The Corporation of Mercer University v. National Gypsum Co., et al.*, 1986 WL 12445 (M.D. Ga. 1986).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is not a proper statement of Georgia law. The cases cited by Plaintiff do not apply to this case. *Borel v. Fibreboard Paper Prods, Corp.* 493 F. 2d 1076 (1973) applies Texas law. Plaintiff cites no case that stands for this proposition under Georgia law. In addition, *The Corporation of Mercer University v. National Gypsum Co*, 1986 WL 12445 (M.D. Ga. 1986) is not applicable. It was a property damage claim over the removal of asbestos and does not stand for the proposition stated in the charge. The charge expands the duty of a manufacturer beyond what is required by Georgia law. The Court refused to give this instruction in *Booker*.

Defendants propose as alternative instruction their proposed instructions on strict liability and negligent failure to warn.

Plaintiff's Response:

The law is correctly stated as set forth in *Mercer, supra*. While *Mercer* was an asbestos case, it stands for the unremarkable and unsurprising proposition that manufacturers of products should, at a minimum, be aware of the knowledge available in the scientific community concerning their products. *Id.* at *2.

PLAINTIFF'S PROPOSED INSTRUCTION RE SCOPE OF DUTY TO WARN

PRODUCTS LIABILITY – MANUFACTURER'S DUTY TO WARN

You must decide whether adequate efforts were made by Bard to communicate all risks that were known to Bard or reasonably should have been known to Bard to the physician who implanted the Eclipse Filter in Mrs. Jones, and whether the warning that Bard communicated was adequate. A warning is inadequate if it does not provide a complete disclosure of both the existence of the risk and the extent of the danger and the severity of any potential injury involved.

Chrysler Corp. v. Batten, 264 Ga. 723, 724 (1994); *Ford Motor Co. v. Stubblefield*, 171 Ga. App. 331, 335 (1984); *Watkins v. Ford Motor Co.*, 190 F. 3d 1213, 1220 (11th Cir. 1999); *Stapleton v. Kawasaki Heavy Indus., Inc.*, 608 F.2d 571, 573 (5th Cir. 1979); *White v. W.G.M. Safety Corp.*, 707 F. Supp. 544, 549 (S.D. Ga. 1988); *Bryant v. Hoffman-La Roche, Inc.*, 262 Ga. App. 401, 410 (2003); *Sands v. Kawasaki Motors Corp.*, 2009 WL 3152859, at *5 (S.D. Ga. Sept. 30, 2009).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is not a proper statement of Georgia law and attempts to extend the duty to warn beyond what is required. It is also duplicative of the instruction on failure to warn and will confuse the jury. Further in a case involving a learned intermediary, the fact the risks were known in the medical community is a factor that should be considered by the jury. *See Wheat v. Sofamor, S.N.C.*, 46 F.Supp.2d 1351, 1363 (N.D.Ga.1999) and *Ellis. C.R. Bard, Inc.*, 311 F.3d 1272 (2002). The Court declined to give this instruction in *Booker*.

Defendants propose as alternative instructions their proposed instructions on strict liability and negligent failure to warn. If the Court is inclined to give this instruction in addition to those, Defendants propose as an alternative instruction:

You must decide whether adequate efforts were made by Bard to communicate the risks that were known to Bard or reasonably should have been known to Bard to the physician who implanted the Eclipse Filter in Ms. Jones, and whether the warning that Bard communicated was adequate. However, in making that determination you make take into account whether the risks were generally known by Dr. Avino and the medical community generally.

Plaintiff's Response:

The proposed instruction correctly states the law and simply advises the jury that a warning that is inadequate if it does not fully disclose the risks and the extent of the danger.

Plaintiff does not object to a modification of the instruction to clarify that the warning must be to physicians, not patients, but believes this topic is adequately covered in other instructions. Plaintiff does object to the blue highlighted portion of Defendants' proposed addition as an improper comment on the evidence.

**PLAINTIFF'S PROPOSED INSTRUCTION RE RISKS TO BE WARNED
ABOUT**

**PRODUCTS LIABILITY – DUTY TO WARN OF KNOWN DANGERS AND
DANGERS THAT SHOULD HAVE BEEN KNOWN**

In considering whether Bard violated its duty to warn, you may consider not only what dangers Bard knew at the time the product was sold, but also what Bard should have known at that time by the application of reasonable, developed human skill.

Bishop v. Farhat, 227 Ga. App. 201, 206 (1997).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is duplicative of the proposed instructions on strict liability and negligent failure to warn. This charge is a paraphrase from *Bishop v. Farhat*, which actually cites to *Chrysler Corp. v Batten*, 264 Ga. 723 (1994). The Georgia Pattern Instruction on strict liability failure to warn is likewise taken from *Batten*. Therefore, there is no need for an additional charge.

Plaintiff's Response:

This instruction is helpful to the jury in understanding the contours of the failure to warn claim and merely instructs (accurately) on the law imposing the duty to warn on Bard.

**DEFENDANTS' REQUEST FOR INSTRUCTION
FAILURE TO READ WARNING**

If a physician does not actually read a warning provided by the manufacturer of a medical device, the adequacy or lack of adequacy of that warning cannot be the proximate cause of the plaintiff's injuries.

Plaintiff's Objection:

This instruction is unnecessary and improper. Questions of causation are for the jury. In addition, Bard had a continuing duty to warn of dangers under Georgia law. Issuance of post-implantation warnings could have allowed for retrieval of Mrs. Jones' filter before it fractured. Ga. Code Ann., Section 51-1-11(C). Further, the instruction is an improper comment on the evidence. It also will be confusing since Dr. Avino testified that he read the IFUs for Bard devices and, even if a jury assumes they are predecessor devices, the warnings are the same for the Eclipse IFU.

Defendants' Response:

Under Georgia law, the failure to warn claim can be based on either the adequacy of the warning or the adequacy of the attempts to communicate the warning. Failure to read a warning prevents recovery on the first part of the claim. "[F]ailure to read instructions or printed warnings will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the product's potential risk." *Wilson Foods Corp. v. Turner*, 218 Ga. App. 74, 75, 460 S.E.2d 532, 534 (1995); *Camden Oil Co., LLC v. Jackson*, 609 S.E.2d 356, 358 (Ga. App. 2004) ("where a plaintiff does not read an allegedly inadequate warning, the adequacy of the warning's contents cannot be a proximate cause of the plaintiff's injuries"). The evidence in the case is that the Eclipse IFU contains different (and contained additional) warnings than the predecessor devices.

INSTRUCTION NO. 18

~~Bard contends that Mrs. Jones' injuries were caused, in whole or in part, by the negligence of Dr. Sarwat Amer. Bard bears the burden of proving Dr. Amer's negligence by a preponderance of the evidence.~~

~~If you find that Mrs. Jones is entitled to recover for her injury, and you further find that Bard has shown that the damages sustained by Mrs. Jones were caused in whole or in part by the negligence of Dr. Amer, you should consider the negligence of Dr. Amer even though he is not a party to this case. The verdict form will instruct you to assign a percentage of fault to Dr. Amer if you conclude that he is at fault. That percentage can be anywhere from zero to 100 percent, and is for you to decide based on the evidence.~~

~~To show that Dr. Amer's negligence caused or contributed to Mrs. Jones' damages, Bard must prove by a preponderance of the evidence that:~~

- ~~(1) — Dr. Amer had a duty of reasonable care to Mrs. Jones,~~
- ~~(2) — Dr. Amer breached that duty,~~
- ~~(3) — the breach was a proximate cause of Mrs. Jones' injury, and~~
- ~~(4) — Mrs. Jones suffered damages.~~

~~In assessing the conduct of Dr. Amer, the following instructions apply:~~

~~(a) — A person professing to practice medicine for compensation must bring to the exercise of the profession a reasonable degree of care and skill. This means such degree of care and skill as, under similar conditions and like surrounding circumstances, is ordinarily employed by the profession generally.~~

~~(b) — If Dr. Amer, in the treatment and care of Mrs. Jones, used that degree of care and skill ordinarily employed by the profession generally under similar conditions and like surrounding circumstances, then Dr. Amer was not negligent. If, on the other hand, Dr. Amer failed to use such degree of care and skill, he was negligent.~~

~~(c) — A doctor is presumed to have performed in an ordinarily skillful manner. Bard may overcome this presumption by introducing evidence that shows by a preponderance of the evidence that Dr. Amer did not treat Mrs. Jones in an ordinarily skillful manner. Expert testimony is required to overcome the presumption.~~

~~(d) — In order to show that Dr. Amer's alleged negligence was a proximate cause of Mrs. Jones' injury, Bard must present expert testimony. An expert's opinion on the~~

~~issue of whether Dr. Amer's alleged negligence caused Mrs. Jones' injury cannot be based on speculation or possibility. It must be based on reasonable medical probability or reasonable medical certainty. If you find that the expert's testimony regarding causation is not based on reasonable medical probability or reasonable medical certainty, then Bard has not proved by a preponderance of the evidence that Mrs. Jones' injury was proximately caused by Dr. Amer's alleged negligence.~~

~~When determining the total amount of Mrs. Jones' damages in this case, if any, you should not reduce the damages because of the negligence, if any, of Dr. Amer. You should instead determine the full amount of Mrs. Jones' damages, and the court, in entering judgment, will allocate those damages according to your allocation of fault among all persons or entities whom you find contributed to Mrs. Jones' damages. The verdict form will help you understand the process of assigning fault.~~

INSTRUCTION NO. 19

—~~There is no contention by Bard that Mrs. Jones is at fault for any of her injuries.~~

INSTRUCTION NO. 29

~~Bard contends that the intervening actions of Dr. Brandon Kang and certain unnamed radiologists constituted superseding causes of Mrs. Jones' injuries.~~

~~A superseding cause is a cause of Mrs. Jones' injuries that breaks the chain of causation between Bard, on one hand, and one or more of Mrs. Jones' injuries, on the other hand. If you find that the actions of Dr. Kang or the radiologists were a superseding cause of one or more of Mrs. Jones' injuries, then Bard cannot be held liable for those injuries.~~

~~For Bard to prove that the intervening actions of Dr. Kang or the radiologists were a superseding cause, Bard must show that their actions constituted the sole proximate cause of one or more of Mrs. Jones' injuries. To make this showing, Bard must prove by a preponderance of the evidence that:~~

- ~~(1) — the actions of Dr. Kang or the radiologists were not foreseeable by Bard,~~
- ~~(2) — the actions of Dr. Kang or the radiologists were not triggered by Bard, and~~
- ~~(3) — the actions of Dr. Kang or the radiologists were sufficient by themselves to cause the injuries.~~

~~If Bard could have reasonably anticipated or foreseen the actions of Dr. Kang or the radiologists, then their actions are not a superseding cause of Mrs. Jones' injuries, even if Bard did not anticipate the details of the actions and the injuries they caused.~~

~~For the actions of Dr. Kang or the radiologists to be a superseding cause, Bard need not prove that they were wrongful or negligent.~~

INSTRUCTION NO. 21

Bard asserts an “assumption of the risk” defense. If Mrs. Jones knew of the Eclipse IVC filter’s defect and was aware of the danger, but nevertheless proceeded unreasonably to make use of the product, taking a risk which in and of itself amounts to a failure to exercise ordinary care for her safety, she cannot later hold Bard responsible for any injury suffered due to taking such a risk.

To establish the defense of assumption of the risk, Bard must prove by a preponderance of the evidence that:

- 1) Mrs. Jones knew of the danger posed by the Eclipse IVC filter,
- 2) Mrs. Jones understood and appreciated the risks of that product, and
- 3) Mrs. Jones knowingly and voluntarily exposed herself to such a risk.

If you find that Bard has proved each of these elements by a preponderance of the evidence, then Mrs. Jones is not entitled to recover for the resulting injury or damages, and you should return a verdict for Bard.

PLAINTIFF'S PROPOSED FDA LIMITING INSTRUCTION

The FDA's review of a medical device depends upon how the device is classified under FDA regulations.

Certain devices are reviewed under FDA's Pre-Market Approval (PMA) process, which approves products focusing on a device's "safety and efficacy."

The FDA's 510(k) process determines whether a device is "substantially equivalent" to another device already legally on the market., it does not evaluate devices for safety and efficacy.

Bard's IVC filters, including Doris Jones' Eclipse IVC filter, were not FDA approved through the PMA process, but were cleared by the FDA through its 510(k) process.

Defendants' Objections:

Defendants object to this instruction on the grounds that it is a comment on facts that should be testified to by witnesses or presented through exhibits. Defendants do not offer an alternative instruction as they do not believe that a statement on the facts or evidence is appropriate

Plaintiff's Response:

Plaintiff responds that this instruction is likely to be appropriate given the emphasis at trial on FDA activity with respect to filter clearance. In submitting this instruction, Plaintiff understands that the Court will evaluate the evidence at trial to determine whether such an instruction is necessary.

**DEFENDANTS' REQUEST FOR INSTRUCTION
JURY DELIBERATION; PRODUCT DEFECT**

If you find by a preponderance of the evidence that the product was defective in design or the adequacy of the warning provided when it left the control of the manufacturer and that the plaintiff's injury was proximately caused by that defect, then you would return a verdict for the plaintiff, unless the plaintiff is denied recovery under some other principle of law given to you in these charges.

If after considering all the evidence, you do not believe by a preponderance of the evidence that the product by which plaintiff claims to have been injured was defective in design or adequacy of the warning when it left the manufacturer's control or that the product was the proximate cause of the plaintiff's injury, then you would end your deliberations; the plaintiff would not be entitled to recover; and you would return a verdict for the defendant.

Georgia Pattern Instruction 62.720 Jury Deliberation; Product Defect

Plaintiff's Objection:

This instruction is unnecessary in light of other final instructions given to the jury. In addition, it is confusing and risks having the jury believe that it must find for Plaintiff on all claims to render a verdict (or both design or both warning claims). There are *four* separate claims and a jury need only find for Plaintiff on *one* of these claims. This instruction muddles that fact.

Defendants' Response:

This is a Georgia pattern instruction that is not encompassed in the instructions as given and provides the jury with necessary guidance on how to proceed during their deliberations.

INSTRUCTION NO. 22

It is the duty of the court to instruct you about the measure of damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Jones on any or all of her claims, you must determine her damages. Mrs. Jones has the burden of proving damages by a preponderance of the evidence. It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on speculation, guesswork or conjecture.

Damages are given as pay or compensation for injury done. Where one party is required to pay damages to another, the law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence that Mrs. Jones is entitled to recover damages, you should award to Mrs. Jones such sums as you believe are reasonable and just in this case.

Necessary expenses resulting from the injury are a legitimate item of damages. As to medical expenses, such as hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expense as was reasonably necessary.

Mrs. Jones seeks to recover not only for her past medical expenses, but also for medical expenses that may be incurred in the future. If you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such future medical expenses, Mrs. Jones would be entitled to recover those amounts, reduced to present cash value.

Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. Questions of whether, how much, and how long Mrs. Jones has suffered or will suffer are for you to decide.

Pain and suffering include mental suffering, but mental suffering is not recoverable as damages unless there is also physical suffering. In evaluating Mrs. Jones' pain and suffering, you may consider the following factors, if proven:

- (1) interference with normal living;
- (2) interference with enjoyment of life;

- (3) impairment of bodily health and vigor;
- (4) fear of extent of injury;
- (5) shock of impact;
- (6) actual pain and suffering, past and future;
- (7) mental anguish, past and future; and
- (8) the extent to which Mrs. Jones must limit activities.

If you find that Mrs. Jones' pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Mrs. Jones will endure. In making such an award, your standard should be your enlightened conscience as impartial jurors. You may take into consideration the fact that Mrs. Jones is receiving a present cash value award for damages not yet suffered.

~~Bard must take Mrs. Jones in whatever condition it finds her. A negligent actor must bear the risk that its liability will be increased by reason of the actual physical condition of the person toward whom its act is negligent. Thus, if you find that Mrs. Jones' injuries were increased by her existing physical condition, you may award damages for those increased injuries provided you find they were proximately caused by Bard.~~

Plaintiff's Objection:

The proposed deletion by Bard omits an important paragraph advising the jury that Bard must take the Plaintiff as it finds her and is not relieved of liability by virtue of any pre-existing conditions Plaintiff has. The Booker instruction adequately addresses this situation and merely sets forth a correct statement of the law. To the extent that Bard establishes that some of Plaintiff's complaints relate to pre-existing conditions, the jury can consider whether Bard's actions or omissions exacerbated those conditions. Decision on this instruction should be deferred until the evidence has been presented so that the appropriateness of the instruction can be assessed in concrete terms.

Defendants' Response:

Defendants deleted and object to the last paragraph of the instruction given in *Booker* as not conformed to the evidence in this case. There is no evidence or testimony that any actions of Bard caused or contributed to Ms. Jones' existing medical conditions.

**DEFENDANTS' REQUEST FOR INSTRUCTION
TORT DAMAGES; DUTY TO LESSEN**

When a person is injured by the negligence of another, she must mitigate her damages as much as is practicable by the use of ordinary care and diligence.

If you find that plaintiff has suffered damages as alleged, under the law, she is bound to reduce those damages, as much as is practicable, by the use of ordinary care. If you believe that by the use of such care that she could have reduced the damages, you would determine to what extent and reduce such damages to that extent.

Georgia Pattern Instruction 66.015 Tort Damages; Duty to Lessen

Plaintiff's Objection:

There is no evidence supporting Mrs. Jones' alleged failure to mitigate her damages. Thus, instructing the jury on this issue will be confusing and contrary to the evidence. See also Plaintiff MILs 1-3.

Defendants' Response:

Plaintiff claims several alleged injuries for which she has received medical care and instruction that she has failed to follow. To the extent that she attributes those to the filter, her failure to follow medical advice or seek medical attention is relevant. O.C.G.A. §51-12-11; *Mallock v. Kicklighter*, 10 Ga. App. 605 (1912).

INSTRUCTION NO. 23

In cases such as this, there may be aggravating circumstances that warrant the award of additional damages called punitive damages. Punitive damages are intended to punish, penalize, and deter wrongful conduct.

Before you may award punitive damages, Mrs. Jones must prove that the actions of Bard showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that would raise the presumption of conscious indifference to consequences.

Mrs. Jones must make this proof by clear and convincing evidence. This is a different and higher burden of proof than a preponderance of the evidence, but is less than the standard of “beyond a reasonable doubt,” which is the proof required in criminal cases. Clear and convincing evidence is defined as evidence that will cause you to firmly believe, to a high degree of probability, that the requirements for punitive damages have been proved.

If Mrs. Jones fails to prove by clear and convincing evidence that Bard was guilty of willful misconduct, malice, fraud, wantonness, oppression, or entire want of care that would raise the presumption of conscious indifference to consequences, then you may not award punitive damages. Mere negligence, even amounting to gross negligence, will not alone authorize an award of punitive damages.

In the verdict form, you will be asked to specify whether Mrs. Jones is entitled to recover punitive damages, but you will not yet be asked to determine an amount of punitive damages. If you decide that she should be awarded punitive damages, then you will receive some brief additional instructions, evidence, and argument before setting the amount.

There can be no recovery of punitive damages in this case unless there is first a recovery by Mrs. Jones of compensatory damages.

INSTRUCTION NO. 24

Before you begin your deliberations, please elect one member of the jury as your presiding juror. The presiding juror will preside over the deliberations and serve as the spokesperson for the jury in court.

You shall diligently strive to reach agreement with all of the other jurors if you can do so. Your verdict must be unanimous.

Each of you must decide the case for yourself, but you should do so only after you have considered all of the evidence, discussed it fully with the other jurors, and listened to their views.

It is important that you attempt to reach a unanimous verdict but, of course, only if each of you can do so after having made your own conscientious decision. Do not be unwilling to change your opinion if the discussion persuades you that you should. But do not come to a decision simply because other jurors think it is right, or change an honest belief about the weight and effect of the evidence simply to reach a verdict.

INSTRUCTION NO. 25

Because you must base your verdict only on the evidence received in the case and on these instructions, I remind you that you must not be exposed to any other information about the case or to the issues it involves. Except for discussing the case with your fellow jurors during your deliberations:

Do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it. This includes discussing the case in person, in writing, by phone or electronic means, via email, via text messaging, or any internet chat room, blog, website or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other forms of social media. This applies to communicating with your family members, your employer, the media or press, and the people involved in the trial. If you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and to report the contact to the court.

Do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it; do not do any research, such as consulting dictionaries, searching the Internet, or using other reference materials; and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in this case, and do not use Internet programs or other devices to search for or view any place discussed during the trial. Also, do not do any research about this case, the law, or the people involved – including the parties, the witnesses or the lawyers – until you have been excused as jurors. If you happen to read or hear anything touching on this case in the media, turn away and report it to me as soon as possible.

As I've explained before, these rules protect each party's right to have this case decided only on evidence that has been presented here in court. Witnesses here in court take an oath to tell the truth, and the accuracy of their testimony is tested through the trial process. If you do any research or investigation outside the courtroom, or gain any information through improper communications, then your verdict may be influenced by inaccurate, incomplete or misleading information that has not been tested by the trial process. Each of the parties is entitled to a fair trial by an impartial jury, and if you decide the case based on information not presented in court, you will have denied the parties a fair trial. Remember, you have taken an oath to follow the rules, and it is very important that you follow these rules.

A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start over. If any juror is exposed to any outside information, please notify the court immediately.

INSTRUCTION NO. 26

The exhibits received in evidence that are capable of being displayed electronically will be provided to you in that form, and you will be able to view them in the jury room. A computer, projector, printer and accessory equipment will be available to you in the jury room.

A court technician will show you how to operate the computer and other equipment; how to locate and view the exhibits on the computer; and how to print the exhibits. You will also be provided with a paper list of all exhibits received in evidence. You may request a paper copy of any exhibit received in evidence by sending a note through the bailiff. If you need additional equipment or supplies or if you have questions about how to operate the computer or other equipment, you may send a note to the bailiff, signed by your presiding juror or by one or more members of the jury. Do not refer to or discuss any exhibit you were attempting to view.

If a technical problem or question requires hands-on maintenance or instruction, a court technician may enter the jury room with the bailiff present for the sole purpose of assuring that the only matter that is discussed is the technical problem. When the court technician or any non-juror is in the jury room, the jury shall not deliberate. No juror may say anything to the court technician or any non-juror other than to describe the technical problem or to seek information about operation of the equipment. Do not discuss any exhibit or any aspect of the case.

The sole purpose of providing the computer in the jury room is to enable you to view the exhibits received in evidence in this case. You may not use the computer for any other purpose. At my direction, technicians have taken steps to ensure that the computer does not permit access to the Internet or to any “outside” website, database, directory, game, or other material. Do not attempt to alter the computer to obtain access to such materials. If you discover that the computer provides or allows access to such materials, you must inform the court immediately and refrain from viewing such materials. Do not remove the computer or any electronic data from the jury room, and do not copy any such data.

INSTRUCTION NO 27

If it becomes necessary during your deliberations to communicate with me, you may send a note through the bailiff, signed by any one or more of you. No member of the jury should ever attempt to communicate with me except by a signed writing. I will not communicate with any member of the jury on anything concerning the case except in writing or here in open court with the parties present. If you send out a question, I will consult with the lawyers before answering it, which may take some time. You may continue your deliberations while waiting for the answer to any question. Please remember that you are not to tell anyone – including the court – how the jury stands, whether in terms of vote count or otherwise, until after you have reached a unanimous verdict or have been discharged. Do not disclose any vote count in any note you may send out to the Court.

INSTRUCTION NO. 28

A verdict form has been prepared for you. [*Explain verdict form as needed.*] After you have reached unanimous agreement on a verdict, your foreperson should complete the verdict form according to your deliberations, sign and date it, and advise the bailiff that you are ready to return to the courtroom.

INSTRUCTION A

Members of the jury, you have decided that Mrs. Jones should be awarded punitive damages. In order to determine the amount of punitive damages, the parties have presented evidence and will now present brief arguments.

The measure of punitive damages is your enlightened conscience as an impartial jury. Any award you make should be both reasonable and just in light of your previous award of compensatory damages, the conduct and circumstances of Bard, and the purpose of punitive damages.

In considering the amount of punitive damages, you may consider the following factors:

- 1) the nature and reprehensibility of Bard's conduct;
- 2) the extent and duration of Bard's wrongdoing and the likelihood of its recurrence;
- 3) the intent of Bard in committing the wrong;
- 4) the profitability of Bard's wrongdoing in Georgia;
- 5) the amount of compensatory damages you have previously awarded;
- 6) the financial circumstances, that is, the financial condition or the net worth of Bard based on the sale of Eclipse filters in Georgia.

In making an award of punitive damages, you should consider the degree of reprehensibility of Bard's wrongdoing. You should consider all of the evidence, both aggravating and mitigating, to decide how much punishment, penalty, or deterrence Bard's conduct deserves in the form of punitive damages. In assessing reprehensibility, you may consider whether:

- 1) the harm caused was physical, as opposed to economic;
- 2) the conduct showed an indifference to or a reckless disregard of the health or safety of others; and
- 3) the conduct involved repeated actions or was an isolated incident.

You may have heard evidence of other conduct and procedures of Bard. For the purpose of punitive damages, you may not consider evidence of any conduct of Bard that

is dissimilar to that which resulted in Mrs. Jones' injury – unless such dissimilar conduct was related to the specific harm suffered by Mrs. Jones in this case.

Plaintiff's Objection:

Neither *State Farm* nor *Gore* limit damages to sales of a product in a particular state. Trial Tr. at 2587. Moreover, Georgia law relating to punitive damages specifically states that there shall be “no limitation” on the amount a jury can award for punitive damages. O.C.G.A. § 51-12-5.1. The concern expressed by the Supreme Court concerning out of state conduct is to ensure that it (1) is not legal in other states and (2) bears some relationship to the conduct at issue in the case. *State Farm*, 538 U.S. at 421-23.

Defendants' Response:

Defendants request these changes (highlighted in blue) to the instruction given in *Booker* comply with the US Supreme Court decisions on punitive damages. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996); *Dimaso v. Ford Motor Company, et. al.*, No. 99-A-6172-6, 2003 WL 22850075, at *1 (Ga. Super. 2003); *Hockensmith v. Ford Motor Co.*, No. 1:01-CV-3645G, 2003 WL 25639639, at *10 (N.D. Ga. Apr. 17, 2003). See also Georgia Suggested Pattern Jury Instructions, Vol. I: Civil Cases, No. 66.770-66.780 (5th ed. 2016).